

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

PBM PHARMACEUTICALS, INC. *et al.*
Plaintiffs,

v.

Civil Action No. 3:14-cv-00016-GEC

METHOD PHARMACEUTICALS, LLC
et al.
Defendants.

**METHOD PHARMACEUTICALS, LLC's ANSWER TO
THIRD AMENDED COMPLAINT**

Defendant Method Pharmaceuticals, LLC ("Method"), through its undersigned attorneys, hereby answers the allegations of Plaintiffs' Third Amended Complaint ("TAC"), solely with respect to Method and not with respect to any other Defendant in the above-captioned matter, as follows:

1. Method lacks information sufficient to form a belief as to whether 1 Plaintiffs' Donnatal brand of pharmaceutical products has helped improve the lives of individuals suffering from irritable bowel syndrome (IBS). Method admits that Paragraph 1 generally describes IBS.

2. Method admits that Plaintiffs distribute Donnatal in a liquid and a tablet formulation. Method denies the remaining allegations contained in Paragraph 2.

3. Method admits that phenobarbital is listed as an active ingredient in Donnatal. Method further admits that atropine, hyoscyamine, phenobarbital, and scopolamine are sometimes referred to as belladonna alkaloids and are also listed as active ingredients in Donnatal. Method lacks information sufficient to form a belief as to the remaining allegations contained in Paragraph 3 and on that basis denies them.

4. Method admits that its products at issue in this case are called Me-PB-Hyos.

Method denies the remainder of the allegations contained in Paragraph 4.

5. Method admits that Plaintiffs purport to seek the relief described in Paragraph 5 but denies that Plaintiffs are entitled to the requested relief, or any relief whatsoever.

6. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 6 and on that basis denies them.

7. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 7.

8. Method admits that it is a Texas limited liability company with its principal office at 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006. Method admits that it is the labeler for the Me-PB-Hyos products at issue in this case.

9. Method admits the allegations contained in Paragraph 9.

10. Method is not required to respond to the allegations in Paragraph 10 because they relate to another defendant. To the extent a response is required, Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 10 and on that basis denies them.

11. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 11.

12. The allegations contained in Paragraph 12 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 12.

13. The allegations contained in Paragraph 13 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 13.

14. The allegations contained in Paragraph 14 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 14 as they relate to Method.

15. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 15.

16. Method admits that Donnatal products are available by prescription only. Method denies all remaining allegations contained in Paragraph 16.

17. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 17.

18. The allegations contained in Paragraph 18 purport to characterize amendments to the Federal Food, Drug and Cosmetic Act (the “FDC Act”) and therefore state legal conclusions to which no response is required. To the extent a response is required, Method states that applicable laws speak for themselves and any characterization thereof is denied. Method lacks information sufficient to form a belief as to the remaining allegations contained in Paragraph 18.

19. The allegations contained in Paragraph 19 purport to characterize a Federal Register notice which speaks for itself and any characterization thereof is denied.

20. Method admits that FDA conditionally approved abbreviated new drug applications for Donnatal tablet and elixir products. The remaining allegations in this paragraph purport to interpret the FDC Act and therefore state legal conclusions to which no response is

required. To the extent a response is required, Method states that applicable laws and regulations speak for themselves and any characterization thereof is denied.

21. Method admits that on May 6, 1983, the FDA published a notice in the Federal Register regarding certain drug products, and that Donnatal was one of the drug products identified in the notice. The remaining allegations in paragraph 21 purport to characterize the Federal Register notice which speaks for itself and any characterization thereof is denied.

22. Method lacks information sufficient to form a belief as to the allegations contained in Paragraph 22 and on that basis denies them.

23. The allegations contained in Paragraph 23 purport to characterize and describe a legal process and state a legal conclusion to which no response is required. To the extent a response is required, Method denies the allegations of the first sentence of Paragraph 23. Method lacks information sufficient to form a belief as to the second sentence of Paragraph 23. Method admits that the NOOH process for Donnatal has not yet been completed.

24. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 24 and on that basis denies them.

25. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 25 and on that basis denies them.

26. Paragraph 26 constitutes Plaintiffs' characterization of the legal implications of an FDA Compliance Policy Guide, which speaks for itself and to which no response is required. To the extent a response is required, Method denies any characterization of the Compliance Policy that is contained in Paragraph 26.

27. Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 27.

28. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 28.

29. Method admits that on or around April 2, 2014, listings for the Me-PB-Hyos products appeared in Medi-Span. Method denies that a listing was attached as Exhibit A to the TAC. Method further states that there is no current Medi-Span listing.

30. Method admits that Medi-Span is a prescription drug and information and interactions database used nationwide by health care professionals, payers and pharmaceutical manufacturers to evaluate medications that are currently or will soon be on the market. Method denies the remaining allegations contained in Paragraph 30.

31. The allegations contained in Paragraph 31 constitute Plaintiffs' characterizations of Medi-Span policies regarding pharmaceutical equivalence and the assignment of a Generic Product Identifier ("GPI"), which speak for themselves and to which no response is required. Method denies characterizations of Medi-Span policies contained in Paragraph 31.

32. Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 32.

33. Paragraph 33 constitutes Plaintiffs' characterization of the Medi-Span listings, which speak for themselves and to which no response is required. Method denies any characterization of the Medi-Span listings contained in Paragraph 33.

34. Method denies the allegations contained in Paragraph 34.

35. Method denies the allegations contained in Paragraph 35.

36. Paragraph 36 constitutes Plaintiffs' characterization of the Medi-Span listing process, which speaks for itself and does not require a response. Method denies any characterization of the Medi-Span listing process contained in Paragraph 36.

37. Method admits that it did not request from FDA, and FDA did not provide, an Approval Letter or approval number for products at issue. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 37.

38. Method admits the allegations contained in Paragraph 38.

39. Method denies the allegations contained in Paragraph 39.

40. Method denies the allegations contained in Paragraph 40.

41. Method denies the allegations contained in Paragraph 41.

42. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 42 and on that basis denies them.

43. Paragraph 43 states a legal conclusion to which no response is required. To the extent that a response is required, Method denies the allegations contained in Paragraph 43. Method states that it listed its products' labeling on DailyMed, a database maintained by the United States National Library of Medicine. Method further states that it listed its products with the United States Food and Drug Administration.

44. Method admits that Medi-Span removed the Me-PB-Hyos listing. Method lacks knowledge or information sufficient to form a belief as to the truth or veracity of allegations contained in Paragraph 44 pertaining to First Databank. Method lacks knowledge or information to form a belief as to the truth or veracity of allegations contained in Paragraph 44 pertaining to the resubmission of Me-PB-Hyos for listing.

45. Method denies the allegations contained in Paragraph 45.
46. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 46 and on that basis denies them.
47. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 47 and on that basis denies them.
48. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 48 and on that basis denies them.
49. Method denies that any introduction of Me-PB-Hyos would be “unauthorized.” Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 49 and on that basis denies them.
50. Method denies the allegations contained in Paragraph 50.
51. The allegations contained in Paragraph 51 constitute legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 51.
52. Method admits that counsel to PBM contacted Method. The remaining allegations contained in Paragraph 52 constitute characterizations of that interaction, and thus legal conclusions to which no response is required. To the extent a response is required, Method denies all characterizations contained in Paragraph 52.
53. The allegations contained in Paragraph 53 constitute legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 53.
54. Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 54, and on that basis denies them.

55. The allegations contained in Paragraph 55 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 55, to the extent they are directed to Method.

56. Method repeats and re-alleges its answers in paragraphs 1 through 55.

57. The allegations contained in Paragraph 57 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 57.

58. The allegations contained in Paragraph 58 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 58.

59. The allegations contained in Paragraph 59 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 59.

60. The allegations contained in Paragraph 60 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 60.

61. The allegations contained in Paragraph 61 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 61.

62. The allegations contained in Paragraph 62 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 62.

63. The allegations contained in Paragraph 63 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 63.

64. Method repeats and re-alleges its answers in paragraphs 1 through 63.

65. Method denies the allegations contained in Paragraph 65.

66. The allegations contained in Paragraph 66 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 66.

67. The allegations contained in Paragraph 67 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 67.

68. The allegations contained in Paragraph 68 are legal conclusions to which no response is required. To the extent a response is required, Method lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 68 and on that basis denies them.

69. The allegations contained in Paragraph 69 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 69.

70. The allegations contained in Paragraph 70 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 70.

71. The allegations contained in Paragraph 71 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 71.

72. Method repeats and re-alleges its answers in paragraphs 1-71.

73. The allegations contained in Paragraph 73 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 73.

74. The allegations contained in Paragraph 74 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 74.

75. The allegations contained in Paragraph 75 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 75.

76. Method repeats and re-alleges its answers in paragraph 1-75.

77. The allegations contained in Paragraph 77 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 77.

78. The allegations contained in Paragraph 78 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 78.

79. Method repeats and re-alleges its answers in paragraphs 1-78.

80. The allegations contained in Paragraph 80 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 80.

81. The allegations contained in Paragraph 81 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 81.

82. Method repeats and re-alleges its answers in paragraphs 1-81.

83. The allegations contained in Paragraph 83 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 83.

84. The allegations contained in Paragraph 84 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 84.

85. The allegations contained in Paragraph 85 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 85.

86. The allegations contained in Paragraph 86 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 86.

87. The allegations contained in Paragraph 87 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 87.

88. The allegations contained in Paragraph 88 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 88.

89. Method repeats and re-alleges its answers in paragraphs 1-88.

90. Method denies the allegations contained in Paragraph 90.

91. Method denies the allegations contained in Paragraph 91.

92. The allegations contained in Paragraph 92 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 92.

93. The allegations contained in Paragraph 93 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 93.

94. The allegations contained in Paragraph 94 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 94.

95. The allegations contained in Paragraph 95 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 95.

96. The allegations contained in Paragraph 96 are legal conclusions to which no response is required. To the extent a response is required, Method denies the allegations contained in Paragraph 96.

Method is not required to respond to Plaintiffs' Prayer for Relief. To the extent a response is required, Method denies the allegations set forth in the Prayer for relief as they relate

to Method and denies that Plaintiffs are entitled to any of the relief requested or any relief whatsoever.

Method denies all allegations in the TAC not specifically admitted above.

AFFIRMATIVE AND OTHER DEFENSES

For further and separate answer, Method alleges as follows:

FIRST DEFENSE

(Failure to State a Cause of Action)

Each cause of action in the TAC fails to state a claim upon which relief can be granted.

SECOND DEFENSE

(First Amendment Rights)

The TAC, and each cause of action therein, is barred to the extent that the conduct alleged is protected by the free speech provision of the United States Constitution.

THIRD DEFENSE

(Good Faith)

Each cause of action is barred, in whole or in part, because Method acted in good faith at all times.

FOURTH DEFENSE

(Lack of Intent)

Plaintiffs' claims based on alleged willful misrepresentations are barred because the representations and actions alleged were not intended to mislead or deceive consumers.

FIFTH DEFENSE

(Lack of Causation)

Each cause of action is barred, in whole or in part, because Plaintiffs have not sustained any injury or damage by reason of any act or omission on Method's part. To the extent that Plaintiffs suffered any damages, such damages were proximately caused by persons, entities, and/or factors or events other than Method and for which Method was and is not responsible.

SIXTH DEFENSE

(Lack of Materiality)

Each cause of action is barred, in whole or in part, because Plaintiffs have not sustained any injury or damage by reason of any material act or admission on Method's part.

SEVENTH DEFENSE

(Lack of Reliance)

Plaintiffs' claims are barred, in whole or in part, because of the lack of reliance by consumers on any alleged misrepresentations by Method.

EIGHTH DEFENSE

(Lack of Awareness)

Plaintiffs' claims are barred, in whole or in part, because consumers lacked awareness of the alleged misrepresentations by Method described in the TAC.

NINTH DEFENSE

(Conduct Not Unlawful)

The business practices relating to the allegations in the TAC are not unlawful.

TENTH DEFENSE

(Competition Privilege)

Any of Method's alleged actions are protected by the privilege of competition in that Method did not use wrongful means to advance a legitimate interest in competing in the free market.

ELEVENTH DEFENSE

(Conduct Not Fraudulent Nor Likely To Deceive)

Method's alleged conduct is not fraudulent and was not likely to mislead or deceive consumers and/or the public.

TWELFTH DEFENSE

(Lack of Materiality)

Plaintiffs' claims based on alleged misrepresentations are barred because the representations alleged by Plaintiffs were not material in that, they were not likely to affect Medi-Span's decisions regarding the listing of the products at issue, and thus were not likely to affect consumers' purchasing decisions. Method's representations and actions alleged in the TAC were not likely to mislead consumers acting reasonably under the circumstances.

THIRTEENTH DEFENSE

(Lack of Standing)

Plaintiffs lack either standing and/or capacity to bring some or all of the claims alleged in the TAC.

FOURTEENTH DEFENSE

(Negligence and Misconduct of Others)

If there was any negligence or other misconduct proximately causing the damages allegedly sustained by Plaintiffs, such negligence or misconduct was that of parties other than Method, and recovery should be barred or eliminated to that extent.

FIFTEENTH DEFENSE

(Adequate Remedy at Law)

Plaintiffs' claims for equitable relief are barred to the extent there is an adequate remedy at law.

SIXTEENTH DEFENSE

(No Right to Injunctive Relief)

To the extent the TAC seeks injunctive relief, Plaintiffs are not entitled to such relief because the hardship that would be imposed on Method, and on the public, by any such relief would be greatly disproportionate to any hardship that Plaintiffs might suffer in its absence. Further, any injunctive relief that would require regulation by this Court on an ongoing basis is inappropriate, and Method's advertising and marketing activities are already monitored by various federal and state agencies.

SEVENTEENTH DEFENSE

(No Right to Punitive or Exemplary Damages)

Plaintiffs are not entitled to punitive or exemplary damages on any cause of action alleged in the TAC. Any award of punitive or exemplary damages would violate the due process and/or equal protection clause of the United States Constitution.

EIGHTEENTH DEFENSE

(Lack of Damages)

Plaintiffs have not suffered any damage as a result of any actions allegedly taken by Method, and are thus barred from asserting any claim against Method.

NINETEENTH DEFENSE

(Federal Preemption)

Plaintiffs' claims are expressly and impliedly preempted by federal law, including but not limited to, the Federal Food, Drug, and Cosmetic Act.

TWENTIETH DEFENSE

(Primary/Exclusive Jurisdiction)

Plaintiffs' claims are barred by the doctrines of primary and/or exclusive regulatory agency jurisdiction.

TWENTY-FIRST DEFENSE

(Unclean Hands)

Plaintiffs' claims are barred or abated substantially by the doctrine of unclean hands

TWENTY-SECOND DEFENSE

(Failure to Mitigate)

Without any admission by Method that Plaintiffs suffered injury in any way, to the extent that Plaintiffs did suffer such injury, their claims are barred in whole or in part because they failed to use reasonable means to prevent the alleged damage and failed to use reasonable means to mitigate their damages.

TWENTY-THIRD DEFENSE

(Reservation)

Method reserves the right to assert additional defenses upon discovery of further information concerning Plaintiffs' claims.

WHEREFORE, Method prays:

1. For a judgment in favor of Method and against Plaintiffs, dismissing the TAC with prejudice;
2. That Method be awarded its costs of suit, including reasonable attorney's fees; and
3. That this Court order such other and further relief in Method's favor as the Court may find just and proper.

Respectfully submitted,

By: /s/
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Counsel for Defendant Method Pharmaceuticals, LLC

Certificate of Service

I hereby certify that on February 27th, 2015, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ E. Kyle McNew

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